OCT - 1 2001

APPENDIX A. 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

Name\Address:

Broncus Technologies, Inc.
1400 N. Shoreline Boulevard,Building A, Suite 8
Mountain View, CA 94043

Telephone Number:

(650) 428-1600

Fax Number:

(650) 428-1542

Contact Person:

Timothy R. Williams
Director, Regulatory and Clinical Affairs

Date Summary was Prepared:

June 29, 2001

Trade Name:

Exhale Probe

Classification Number and Name:

Class II, 21 CFR 892.1560, Ultrasound Pulsed Echo Imaging System

Class II, 21 CFR 892.1570, Diagnostic Ultrasound Transducer

Class II 21 CFR 874.4680, Bronchoscope & Accessories

Device Description:

The *Exhale Probe* is a multi-function catheter that provides: (1) Doppler audio output in the presence of pulmonary vessel blood-flow; and (2) radiofrequency (RF) energy to a target site within the upper airway or tracheobronchial tree. The probe is inserted into through the 2 mm working channel of a standard bronchoscope and connects to the Exhale Doppler Processing Unit and a standard, commercially available, electrocautery radiofrequency generator.

Substantial Equivalence:

The *Exhale* Probe is substantially equivalent to the Exhale Doppler Probe (K010649) and the Exhale RF Probe (K011267). with respect to intended use, method of introduction, method of operation, safety, and materials.

Safety:

The *Exhale* Probe consisting of a multi-function catheter contains a coagulation electrode and an ultrasonic transducer and is designed to comply with International Standard IEC 60601-1. The *Exhale* Probe will meet the requirements of the FDA's 510(k) Diagnostic Ultrasound Guidance for 1997 for a Track 1 device.

Non-Clinical Test Results:

Biocompatibility
The materials used in the *Exhale* RF Probe have proven biocompatibility.

Summary of Substantial Equivalence:

Based on the intended use and product performance information provided in this notification, the subject device has been shown to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 1 2001

Broncus Technologies, Inc.
C/O Mark Job
TÜV Product Services
1775 Old Highway 8
New Brighton, MN 55412-1891

Re: K013111
Trade Name: Exhale Probe
Regulation Number: 21 CFR 874.4680; 21 CFR 892.1570; 21 CFR 892.1560
Regulation Name: Bronchoscope and Accessory; Diagnostic Ultrasound Transducer; Ultrasound Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: EOQ; ITX; IYO
Dated: September 17, 2001
Received: September 18, 2001

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the Model BT 1440 transducer intended for use with the Exhale Probe Catheter, as described in your premarket notification.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Karen Baker MSN, RN at (301) 594-2080.

Sincerely yours,

for A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

510(k) Number (if known): K 013111

Device Name: The *Exhale* Probe

Indications for Use: The *Exhale* Probe is intended for blood-flow detection and electrosurgery procedures (i.e. coagulation/cauterization, hemostasis, etc.) in the upper airways and tracheobronchial tree through a bronchoscope.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR over-the-counter Use _____

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K013111